

Attorney Docket No.: **RTS-0253**
Inventors: **Susan M. Freier**
Serial No.: **09/975,123**
Filing Date: **October 9, 2001**
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REMARKS

Claims 1-10 and 12-15 are pending in the instant application. Claims 1-10 and 12-15 have been rejected. Claims 1-10, 12, 14 and 15 have been amended. New claim 21 has been added to incorporate subject matter removed from claim 3. No new matter has been added by these additions and amendments to the claims. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims Under 35 U.S.C. 102(a)

The rejection of claims 1-5 and 11-19 under 35 U.S.C. 102(a) as being anticipated by Miyake et al. (WO 01/05435 A2) has been maintained. The Examiner suggests that this patent application discloses intraperitoneal administration of compositions comprising antisense oligonucleotides targeted to mouse insulin-like growth factor binding protein 5 and inhibition of this gene in mouse tumor cells, where the antisense compounds are modified as claimed and comprise a pharmaceutically compatible carrier. The Examiner suggests that the patent discloses antisense that aligns with SEQ ID NO's 14, 16, 17, 19, 21 and 25 of the instant invention.

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At the outset, the claims have been amended to remove reference to compounds comprising SEQ ID NO's 14, 16, 17, 19, 21 or 25 and to recite compounds targeting nucleobase regions other than those targeted by these same sequences.

The patent application discloses a method for treating hormone-regulated tumors in mammals by administration of antisense oligonucleotides targeting murine and human insulin-like growth factor binding protein 5 genes. Nowhere does this patent application teach or suggest antisense compounds that target the nucleobase regions of the insulin-like growth factor binding protein 5 nucleic acid molecules as now claimed. Further, nowhere does this patent application teach or suggest the exact sequences of SEQ ID NO's 14, 16, 17, 19, 21 or 25 as now claimed. Accordingly, this patent fails to teach the limitations of the claims as amended and cannot anticipate the instant invention (MPEP 2131). Withdrawal of this rejection is respectfully requested.

II. Rejection of Claims Under 35 U.S.C. 112, Second Paragraph

Claims 1-10 and 12-15 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly

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regards as the invention. The Examiner suggests that the metes and bounds of the term "compound" in claim 1 cannot be determined and that clarification is requested. Applicant respectfully points out that the term is defined by the language of the claim as something that is 8 to 50 nucleobases in length and which is targeted to specific regions within specific sequences that are listed by SEQ ID NO. Therefore, the claim as filed specifically defines a "compound" of the claimed invention. However, in an earnest effort to advance the prosecution, Applicant has amended the claims to recite "an antisense compound". Support for this amendment can be found throughout the specification as filed. Withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims Under 35 U.S.C. 112, First Paragraph

Claims 1-10 and 12-15 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed

It is respectfully suggested that the term "antiprotein/exon

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does not adequately describe the attributes necessary for such a region. Further, the Examiner suggests that the specification, while being enabling for compositions and methods for inhibiting the expression of ILGFRP5 of SEQ ID NO's 3 or 10 *in vitro* does not reasonably provide enablement for any oligonucleotide targeting any or all intron/exon junction regions of SEQ ID NO: 11, nor for the *ex vivo* administration of antisense. As such, the Examiner has rejected claims 1-10 and 12-15 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant respectfully traverses these rejections under 35 U.S.C. 112, first paragraph.

At the outset, Applicants have amended the claims to recite that the intron/exon junction regions claimed are regions with specific nucleobase numbers and that the method of claim 15 is for *in vitro* use of the claimed compounds by inserting the term *in vitro* also into the preamble of claim 15. Support for these amendments can be found throughout the specification as filed but

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Accordingly, withdrawal of the rejection is requested in light of these amendments.

IV. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: June 10, 2003

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June 10, 2003

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FAX NUMBER: 1-703-872-9306

ATTORNEY DOCKET NO.: RTS-0253

SERIAL NO.: 09/975,123

FILED: October 9, 2001

NUMBER OF PAGES: 12
(including this sheet)

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